K063191

HEIDELBERG ENGINEERING

510(k) Summary of Safety and Effectiveness

OCT 31 2006

Manufacturer and Submitter

Company Name:	Heidelberg Engineering GmbH
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Contact Person:	Dr. Gerhard Zinser
Date Summary Prepared:	September 11, 2006

Device

Trade/Device Name:	HRA 2 / OCT
Common/Usual Name:	Heidelberg Retina Angiograph / Optical Coherence Tomograph
Classification Name:	Opthalmoscope, AC-powered
Regulation Number:	21 CR 886.1570
Product Code:	HLI
Classification Panel:	Ophthalmic
Classification:	Class II device

Substantial Equivalence

The OCT add-on to the HRA 2 is substantially equivalent to the Carl Zeiss Ophtalmic Systems Inc. Humphrey Octical Coherence Tomographer 3, Humphrey OCT3, a 510 (k) cleared device (K012727).

Device Description

The HRA 2 / OCT is an add-on to the Heidelberg Retina Angiograph (HRA 2). It is intended for the imaging of the retina and retinal structures.

With the additional HRA 2 / OCT it is possible to perform axial cross sectional images of the retina or 3-dimensional volume scans of the retina. The visible structures are distinguished on the basis of their varying optical characteristics at the light wavelength used. The intensity of the back-reflected light is measured and displayed as gray-values on a computer monitor.

The light sent to the probe interferes with the light that is back-reflected from the probe. The optical interference of both light beams is detected and the spectrum of the light is analyzed in an optical spectrometer. This technology is called spectral-domain optical coherence tomography (SD-OCT) or Fourier-domain OCT (FD-OCT).

The images acquired by the device can be displayed, edited and stored using the Heidelberg Eye Explorer Software.

Intended Use

The OCT add-on to the HRA 2 is intended for use for the imaging of the retina and retinal structures, and for aiding in the assessment and management of various diseases of the posterior segment, such like age-related macula degeneration, diabetic retinopathy, and glaucoma.

Technological Characteristics Compared to Predicate Device

Comparison items	HRA 2 / OCT	OCT 3
k number		K012727
Indications for use	The OCT add-on to the HRA 2 is a decvice for the optical imaging of posterior ocular structures. The Device uses Octical Low Coherence Tomography technology for the axial cross sectional imaging of the retina. The OCT add-on to the HRA 2 is intended for use for the imaging of the retina and retinal structures, and for aiding in the assessment and management of various diseases of the posterior segment, such like age-related macula degeneration, diabetic retinopathy, and glaucoma.	The Humphrey OCT3 is a high resolution tomographic device for the vieweing and axial cross sectional imaging of posterior ocular structures. It is used for the in vivo imaging and measurement ot the retina, retina nerve fiber layer and optic disk. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases, including but not limited to macular edema, central serous retinopathy and glaucoma.
Corneal contact	No	No
Working distance cornea to objective	Ca. 10 mm	No information
Corneal contact sensing and warning feature	No	No
Pre-sterilized contact surface	No	No

Comparison of similarities and differences continued:		
Comparison items	**HRA 2 / OCT**	**OCT 3**
k number		**K012727**
Front surface area	310 mm^2	No information.
Focus	Manually adjustable	Manually adjustable
Focus adjustment range	Correction of patients refractive errors: -12 to +12 diopters	Correction of patients refractive errors: -12 to +12 diopters
Alignment to patient	Device is adjusted horizontally and vertically while the patient is sitting straight in front of the device.	Device is adjusted horizontally and vertically while the patient is sitting straight in front of the device.
Working position	The patient is sitting straight in front of the device. The examiner is sitting opposite to the patient.	The patient is sitting straight in front of the device. The examiner is sitting opposite to the patient.
Optical setup	Frequency (Fourier) Domain OCT	Time Domain OCT
Type of scanning aperture	Point scan.	Point scan.
Scanning means	Galvanometric scanning motor.	Galvanometric scanning motor
Light source	SLD, 870 nm, Class 1	SLD 820 nm, Class 1
Optical resolution, lateral	14 µm	20 µm in tissue (spot size in tissue)
Optical resolution, depth	6,9 µm	<10 µm in tissue

Comparison of similarities and differences continued:		
Comparison items	**HRA 2 / OCT**	**OCT 3**
k number		**K012727**
Detector	Linear line array	Photodiode
Lateral field of view	**2D Scan:** 3 mm to 9 mm, corresponding to 10° to 30° **3D Scan:** 1,5 mm x 1,5 mm to 9 mm x 9 mm, corresponding to 5° x 5° to 30° x 30°	**2D Scan:** 6 mm, corresponding to 20°
Lateral digital resolution	**2D Scan:** high resolution mode: 5 µm high speed mode: 10 µm **3D Scan:** high resolution mode: 5 µm high speed mode: 35 µm video mode: 25 µm to 150 µm	**2D Scan:** 8 µm (768 A scan in 6 mm)
Depth digital resolution	3 µm (512 points in 1,5 mm in tissue)	2 µm (1024 points in 2 mm in tissue)

Comparison of similarities and differences continued:		
Comparison items	**HRA 2 / OCT**	**OCT 3**
k number		**K012727**
Image acquisition time	**2D Scan:** high resolution mode: 6 to 20 ms high speed mode: 12 to 40 ms **3D Scan:** high resolution mode: 3,6 s high speed mode: 1,6 s video mode: 0,1 s	**2D Scan:** 0,32 s to 1,92 s (depends on no. of A-scan)
Acquisition of three-dimensional images	Yes	No
Image storage	Directly into PC RAM, then to PC hard disk drive	No information
Image compression method	Yes (without information loss)	No information
Operating and image management software	Custom	Custom

Comparison of similarities and differences continued:		
Comparison items	**HRA 2 / OCT**	**OCT 3**
k number		**K012727**
Physical layout	- Mount with headrest - Optical head - Power supply and laser unit - Touchpanel - Computer with monitor, keyboard, Mouse and printer - Lift table	- Imaging device with integrated headrest - Computer with monitor, keyboard, Mouse and printer - Lift table

Conclusions from Performance Testing

The HRA 2 / OCT has been tested according to IEC 60601-1 and IEC 60601-1-2, and was found to meet all requirements. The system is a laser product of Class 1 according to 21 CFR Part 1040 Section 1040.10 and IEC 60825-1:1993+A2:2001.
The evaluation of the device and comparison of acquired images resulted in substantial equivalence to the predicate devices with respect to intended use, technological characteristics, and safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2007

Heidelberg Engineering GmbH
c/o Mr. Morten Simon Christensen
Underwriters Laboratories, Inc
455 E. Trimble Road
San Jose, CA 95131-1230

Re: K063191
Trade/Device Name: Heidelberg Retina Angiograph 2/ Optical Coherence Tomograph (HRA 2/OCT)
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: II
Product Code: OBO
Dated: October 18, 2006
Received: October 20, 2006

Dear Mr. Christensen:

This letter updates our substantially equivalent letter of October 31, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your

device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Evenette Y Beans PhD

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

HEIDELBERG ENGINEERING

Indication for Use

510(k) Number (If known):

Device Name: Heidelberg Retina Angiograph 2 / Optical Coherece Tomograph (HRA 2 / OCT)

Indication for Use The OCT add-on to the HRA 2 is intended for use for the imaging of the retina and retinal structures, and for aiding in the assessment and management of various diseases of the posterior segment, such like age-related macula degeneration, diabetic retinopathy, and glaucoma.

Prescription Use X and / or Over-The –Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Dennis L. McCarthy

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K063191